

1 HEART FAILURE MITRAL ANNULOPLASTY RING  
2 WITH MULTIPLE SETS OF SUTURE PLACEMENT INDICIA  
3

4 BACKGROUND OF THE INVENTION  
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6 1. Field of the Invention

7 This invention relates broadly to implantable  
8 prostheses. More particularly, this invention relates to  
9 annuloplasty rings specifically adapted for the mitral  
10 valve of the heart.  
11

12 2. State of the Art

13 Mitral regurgitation is a "leaking" of the mitral  
14 valve which connects the left atrium and the left ventricle  
15 of the heart. When the left ventricle contracts to eject  
16 blood to the rest of the body, the mitral valve closes to  
17 prevent blood from passing in the wrong direction; i.e.,  
18 into the left atrium. When the mitral valve fails to close  
19 properly and mitral regurgitation (MR) develops. If the MR  
20 is severe, mitral valve repair or replacement is needed to  
21 preserve the function of the left ventricle and to prevent  
22 congestive heart failure from developing. Mitral valve

1 repair is often done to eliminate MR and prevent the  
2 necessity of mitral valve replacement.

3  
4 During mitral valve repair, a portion of the redundant  
5 valve tissue is resected and the valve leaflets are  
6 reshaped to eliminate MR. In degenerative disease of the  
7 mitral valve leaflets, the annulus about the leaflets  
8 typically increases by approximately one hundred to two  
9 hundred percent. In such case, an annuloplasty ring is  
10 provided at the annulus and the annulus is sewn to the ring  
11 to create a purse string effect around the base of the  
12 valve which helps the leaflets meet when the valve closes.  
13 This also restores the anatomical size and shape of the  
14 valve and supports the repaired mitral valve to prevent  
15 recurrent dilatation. Due to the excess leaflet tissue  
16 caused by degenerative disease, any size mismatching of the  
17 annuloplasty ring and the mitral annulus is of little  
18 consequence.

19  
20 However, in heart failure, the leaflets are not  
21 enlarged. Thus, choosing the appropriate size for an  
22 annuloplasty ring is critical to avoid the occurrence of MR  
23 from continuing dilatation of the heart.

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2        Each of the anterior and posterior leaflets of the  
3 annulus is divided by nomenclature into thirds. The  
4 anterior leaflet has a leftmost portion  $A_1$ , a central  
5 portion  $A_2$ , and a rightmost portion  $A_3$ . Similarly, the  
6 posterior anterior leaflet has a leftmost portion  $P_1$ , a  
7 central portion  $P_2$ , and a rightmost portion  $P_3$ . early  
8 leakage of the mitral valve in heart failure starts at two  
9 specific locations, namely  $P_1$  and  $P_3$ . However,  $P_2$  is the  
10 portion directly in the path of blood from the left atrium  
11 to the ventricle.

12

13        It has been noted by the present inventor that prior  
14 art mitral annuloplasty rings effect an undesirable  
15 gradient across the mitral valve which may cause a backflow  
16 of blood into the lungs. Prior art mitral annuloplasty  
17 rings remodel the annulus by providing a 3:4 ratio between  
18 the anteroposterior and transverse diameters of a normal  
19 mitral valve for what is generally considered optimal  
20 hemodynamic performance. In addition, the outer cross-  
21 sectional diameter of a state of the art ring is relatively  
22 uniform about its circumference.

23

1        Annuloplasty rings are typically made of flexible  
2 polymers and generally are available in ring-shaped  
3 (annular) or C-shaped configurations. The C-shaped designs  
4 include a posterior portion (including substantially  
5 transverse lateral portions and a central portion  
6 therebetween), but no anterior portion, which operates to  
7 effect a reduced gradient (but does not eliminate the  
8 gradient). In addition, some annuloplasty rings, e.g., the  
9 Sulzer Carbomedics AnnuloFlex™ ring and the St. Jude  
10 Medical Tailor™ ring, have a ring-shaped configuration that  
11 is adapted to be converted into a C-shaped configuration by  
12 removal of the anterior portion of the ring. Annuloplasty  
13 rings generally also include commissure guides (or trigone  
14 markings) by which to reference a ring relative to the left  
15 and right valve leaflet commissures (or left and right  
16 fibrous trigones) and the posterior midline of the valve  
17 annulus to facilitate implantation.

18

19        Annuloplasty rings are also available in a variety of  
20 sizes permitting selection of a ring which most  
21 appropriately corresponds to the intended size of the post-  
22 operative annulus. However, this requires that a medical  
23 care facility stock each of the variety of sizes, thereby

1 complicating inventory control. Each size of ring includes  
2 thereon, or has associated therewith a guide which  
3 includes, markings indicating spaced-apart locations for a  
4 set of suture ties so that the ring can be coupled to the  
5 mitral valve annulus.

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#### SUMMARY OF THE INVENTION

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9       It is therefore an object of the invention to provide  
10 an annuloplasty ring that can produce multiple degrees of  
11 valve area reduction by having spaced-apart markings  
12 producing different degrees of reduction of the annulus,  
13 thereby obviating the need to stock as many sizes of rings  
14 as in the prior art.

15

16       It is another object of the invention to provide an  
17 annuloplasty ring which provides desirable hemodynamic  
18 performance.

19

20       It is a further object of the invention to provide an  
21 annuloplasty ring which reduces a gradient across the valve  
22 to physiological levels.

23

1       It is also an object of the invention to provide an  
2 annuloplasty ring which can be used in a ring-shaped  
3 configuration, a C-shaped configuration, and other  
4 configurations most suitable to treat mitral regurgitation.  
5

6       In accord with these objects, which will be discussed  
7 in detail below, an annular mitral annuloplasty ring  
8 includes an anterior portion and a posterior portion having  
9 central and substantially transverse lateral portions.  
10 Alternatively, the ring may be C-shaped and formed without  
11 the entirety of, or a portion of, the anterior portion.  
12

13       Regardless of whether the ring is completely annular  
14 or C-shaped, according to a first preferred aspect of the  
15 invention, the ring includes a posterior portion defining a  
16 central portion and two lateral portions. The ring is  
17 adapted in construction for stabilization and non-reduction  
18 of the central posterior portion, while significant  
19 reduction of lateral portions is facilitated. It has been  
20 determined by the inventor that, in many cases, reduction  
21 of the central posterior portion of the ring results in an  
22 increased gradient. Therefore, the ring of the invention  
23 does not reduce, but only stabilizes the central portion of

1 posterior leaflet, and consequently decreases the gradient  
2 across the valve relative to prior art rings which cinch a  
3 central posterior portion of the valve annulus.

4

5       According to a second preferred aspect of the  
6 invention, the construction of the ring at the lateral  
7 posterior portion is different than the construction at the  
8 central posterior portion (i.e., the portion adapted to  
9 optionally be removed). The lateral posterior portions are  
10 substantially stiffer than the central posterior portion.  
11 A softer central posterior portion minimizes a gradient  
12 where the central posterior portion remains integral with  
13 the ring, while the lateral posterior portions contribute  
14 strength and competence of the valve during closure of the  
15 leaflets. One preferred manner of effecting stiffer  
16 lateral posterior portions is to construct the sides as  
17 relatively flatter than a more tubular central portion.

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19       From the foregoing, it is appreciated that the mitral  
20 annuloplasty ring of the invention is hemodynamically  
21 optimized to reduce a gradient thereacross, and improve  
22 competence of the valve leaflets by selectively reducing  
23 the lateral posterior portions.

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According to a third preferred aspect of the invention, the ring includes indicia of multiple sets of suture markings, each set identifying a plurality of suture locations about the perimeter of the ring which are adapted to cinch the annulus by a predetermined amount about the ring. Thus, a single ring may be used to cinch the annulus in accord with relatively different degrees of desired valve area reduction. This is in contrast to the prior art, where multiple rings of different dimensions are required for the same effect. Thus, each ring of the invention corresponds to multiple rings of different sizes and reduction capabilities of the prior art.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.



## BRIEF DESCRIPTION OF THE DRAWINGS

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Fig. 1 is a plan view of an mitral annuloplasty ring according to the invention;

Fig. 2 is a cross-section across line 2-2 in Fig. 1;

Fig. 3 is a cross-section across line 3-3 in Fig. 1;

Fig. 4 is a cross-section across line 4-4 in Fig. 1;

Fig. 5 illustrates the mitral annuloplasty ring of the invention shown implanted, where both the anterior and posterior portions of the ring are used;

Fig. 6 illustrates the mitral annuloplasty ring of the invention shown implanted, where the anterior portion of the ring is removed;

Fig. 7 illustrates the mitral annuloplasty ring of the invention shown implanted, where both the anterior portion and central posterior portions of the ring are removed,

1 leaving only the lateral posterior portions of the ring  
2 implanted at the valve;

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4 Fig. 8 is a second embodiment of a mitral valve  
5 annuloplasty ring according to the invention; and

6

7 Fig. 9 is an embodiment of a instrument which includes  
8 suture guides in accord with the invention.

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10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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12 Turning now to Fig. 1, a mitral annuloplasty ring 10  
13 is shown. The ring 10 includes a shallowly curved anterior  
14 portion A, and a steeper curved posterior portion P. The  
15 ring is preferably provided with trigone guides 12, 14 (or  
16 alternatively commissure guides) and optionally a posterior  
17 midline guide 16 which together facilitate alignment of the  
18 ring relative to anatomical landmarks of the mitral valve.  
19 Referring to Figs. 2 through 4, the ring 10 is preferably  
20 constructed of an inner structural constituent 18, e.g.,  
21 resilient polytetrafluoroethylene (PTFE), which is  
22 surrounded by a fabric outer layer 20 through which suture  
23 needles and suture can be passed to secure the ring at the

1 valve annulus. Other materials known in the art can also  
2 be used in the alternative or in combination with the above  
3 described materials.

4

5 According to a first preferred aspect of the  
6 invention, the posterior portion P includes a central  
7 portion  $P_2$  and substantially transverse lateral portions  $P_1$   
8 and  $P_3$  on either side of the central portion. The ring 10  
9 is preferably adapted in construction for optional removal  
10 of the central posterior section  $P_2$ , preferably after  
11 implantation of the ring at the valve (See Fig. 7). That  
12 is, the ring 10 at the junction of  $P_1$  and  $P_2$  and junction of  
13  $P_2$  and  $P_3$  preferably includes indicia 22, 24 indicating  
14 where a blade may be used to cut the ring and/or is  
15 provided with a weakened section (e.g., reduced diameter),  
16 or even a discontinuity, of the structural constituent 18  
17 at the indicated locations 22, 24 to facilitate cutting and  
18 removal of the central posterior portion  $P_2$ . If removal of  
19 the central portion  $P_2$  is performed, it is preferably  
20 performed after suturing the lateral posterior portions  $P_1$   
21 and  $P_3$  at the valve annulus. It has been determined by the  
22 inventor that, in many cases, the central posterior portion  
23  $P_2$  of the ring 10 is not required to abate MR or support the

1 annulus and may, in fact, contribute to an excessive  
2 gradient across the ring 10. By eliminating the central  
3 posterior portion  $P_2$ , the gradient is reduced relative to  
4 prior art to thereby provide superior results.

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6       It has also been determined by the inventor that, in  
7 many cases, reduction of the  $P_2$  of the valve annulus  
8 contributes to an excessive gradient across the ring 10.  
9 The  $P_2$  portion of the ring 10 includes suture markings 21  
10 (represented by circles) which are spaced so as to effect  
11 no annular reduction if the  $P_2$  portion of the ring is kept  
12 intact and coupled to the valve. By not reducing the  
13 central posterior portion  $P_2$ , the gradient is reduced  
14 relative to prior art to thereby provide superior results.  
15 In addition, similarly spaced-apart markings 23 (also  
16 represented by circles) between indicia 12 and 14 (Fig. 1)  
17 of the anterior leaflet are provided so as to not effect  
18 reduction of the anterior annulus.

19

20       Referring to Figs. 2 through 4, and according to a  
21 second preferred aspect of the invention, the construction  
22 of the ring at the lateral posterior portions  $P_1$  and  $P_3$  is  
23 different than the construction at the central posterior

1 portion  $P_2$ . The lateral posterior portions  $P_1$ ,  $P_3$  are  
2 slightly stiffer than the central posterior portion  $P_2$ . One  
3 preferred manner of effecting stiffer lateral portions  $P_1$   
4 and  $P_3$  is to construct the sides relatively flatter, and the  
5 central posterior portion  $P_2$  more cylindrical. That is, the  
6 lateral posterior portions  $P_1$  and  $P_3$  preferably have a  
7 smaller dimension in the direction of blood flow and a  
8 relative greater dimension transverse to the direction of  
9 blood flow. The more flexible central posterior portion  $P_2$   
10 minimizes a gradient where the central posterior portion  
11 remains integral with the ring after implantation. In  
12 addition, the lateral posterior portions  $P_1$ ,  $P_3$  contribute  
13 strength, but do not significantly affect the gradient.  
14 The similarly structured more flexible anterior portion  
15 allows preservation of normal annular movement during the  
16 cardiac cycle.

17

18 From the foregoing, it is appreciated that the mitral  
19 annuloplasty ring of the invention is hemodynamically  
20 optimized to reduce a gradient thereacross.

21

22 Referring back to Fig. 1, according to a third  
23 preferred aspect of the invention, the ring 10 includes

1 multiple circumferential sets 26, 28 of indicia (where only  
2 a subset of each set of indicia is identified by the  
3 reference numerals) for suture placement. Fig. 1  
4 distinguishes the sets of indicia based upon a discrete  
5 shape (e.g., circles 26 and cruciforms 28) for ease of  
6 distinction in the black and white drawing. However,  
7 distinctions based upon discretely colored markings (e.g.,  
8 colored sutures extending circumferentially about the ring)  
9 or other visual indicators may be preferred. Each marking  
10 within a set 26, 28 is preferably spaced apart from another  
11 marking of the same set by a predetermined distance (e.g.,  
12 2.5 mm or 3.0 mm or similar increments). Each set 26, 28  
13 of indicia thusly corresponds to a predetermined amount of  
14 cinching about the ring 10. The physician selects one of  
15 the plurality of sets of markings according to the degree  
16 by which the physician assesses that the valve annulus  
17 should be cinched. Thus, a single ring may be used to  
18 cinch the annulus in accord with relatively different  
19 degrees of desired valve area reduction. In contrast, the  
20 prior art would require different rings each optimized for  
21 a different size of reduction.

22

1       Alternatively, the indicia corresponding to multiple  
2 sets of suture locations sizes may be provided to  
3 instrumentation, such as a ring holder to thereby guide the  
4 surgeon to the same effect. For example, instrument 50  
5 includes a handle 52 having a manual gripping element 54 at  
6 one end and a ring holder 56 removably coupled at its other  
7 end. Such ring holders are well known in the art. In  
8 accord with the invention, the ring holder 56 is coupled to  
9 a ring 10, e.g., with sutures (not shown), and includes  
10 multiple sets of suture guides 58 (circles), 60  
11 (cruciforms) along portions of the holder 10 which  
12 correspond to the  $P_1$  and  $P_3$  portions of the ring 10. The  
13 portions of the holder 10 which correspond to the  $P_3$  and  
14 anterior portions of the ring 10 are each preferably  
15 provided with a single set of suture guides 62 (along  $P_3$ )  
16 and 64 (along the anterior portion).

17

18       An annuloplasty ring 10 according to the invention may  
19 be implanted in any of three configurations at the mitral  
20 valve. Referring to Fig. 5, in accord with the a first  
21 method of implantation, the valve annulus 40 is sutured to  
22 both the anterior and posterior portions A and P of the  
23 ring 10. Thus, the ring 10 is circumferentially continuous

1 (with the anterior portion A intact) in its implanted  
2 state. Referring to Fig. 6, in a second method of  
3 implantation, the valve annulus 40 is sutured to the  
4 posterior portions  $P_1$ ,  $P_2$  and  $P_3$  of the ring 10, and the  
5 anterior portion of the ring is removed from the implant,  
6 e.g., by cutting. While the central posterior portion  $P_2$   
7 remains intact, the structural design of this portion  
8 operates to limit the gradient across the anterior portion  
9 of the valve. Referring to Fig. 7, in a third method of  
10 implantation, the valve annulus is sutured to the lateral  
11 posterior portions  $P_1$  and  $P_3$  of the ring, but not the  
12 central posterior portion  $P_2$  or the anterior portion A. The  
13 central posterior portion  $P_2$  and anterior portion A are then  
14 removed from the ring after the valve annulus is secured to  
15 the lateral posterior portions  $P_1$  and  $P_3$ . As the ring is  
16 structurally stiffer along the lateral posterior portions,  
17 the annulus is nevertheless stably supported. Moreover,  
18 removal of the central posterior portion  $P_2$  greatly reduces  
19 the gradient across the valve and provides a superior  
20 result relative to prior art annuloplasty rings. Thus, the  
21 invention includes a method whereby the lateral posterior  
22 portions of an annulus are supported by an implant, but the  
23 anterior and central posterior portion of the annulus are



1 unsupported by an implant so as to reduce a gradient across  
2 the mitral valve.

3

4 Turning now to Fig. 8, another embodiment of an  
5 annuloplasty ring according the invention is shown. The  
6 ring 110 is C-shaped and formed without a significant  
7 portion of the anterior portion A or even the entirety  
8 thereof. Preferably, all other features of ring 10, e.g.,  
9 a construction permitting removal of central portion P<sub>2</sub> and  
10 a plurality of sutures sets, are incorporated into ring  
11 110. The ring may be implanted in accord with the methods  
12 described with respect to Figs. 6 and 7.

13

14 There have been described and illustrated herein  
15 embodiments of an annuloplasty mitral valve ring and a  
16 method of annuloplasty. While particular embodiments of  
17 the invention have been described, it is not intended that  
18 the invention be limited thereto, as it is intended that  
19 the invention be as broad in scope as the art will allow  
20 and that the specification be read likewise. It will  
21 therefore be appreciated by those skilled in the art that  
22 yet other modifications could be made to the provided

- 1 invention without deviating from its spirit and scope as
- 2 claimed.